Remarks

Claims 1-14 are pending in the application.

With this amendment, claims 1, 5, 6, and 9 are amended; claims 15 through 25 are canceled; and new claims 26 through 31 are added.

Claims 1 through 14 and 26 through 31 remain in the application for consideration.

Reconsideration and allowance of the claims as amended in light of the following remarks, are respectfully requested.

The amendments to claims 1, 5, 6, and 9, and the new claims, are fully supported by the specification as originally filed, e.g., based on the following:

The amendments to claims 1, 5, 6, and 9 are supported, e.g., at figure 4.

Support for claim 26 can be found, for example, at page 7, lines 10-27, and at figures 1 and 5.

Support for claim 27 can be found, for example, at original claim 2, and at figures 4a, 5a, and 6a.

Support for claim 28 can be found, for example, at page 7, lines 14-18.

Support for claim 29 can be found, e.g., at the Example, which describes sealing a bladder by use of a device of the invention by checking for leaks and re-adjusting the anastomosis device if necessary to prevent leakage. See also page 6, lines 4 through 17, which describes steps of a method that include using tissue approximating structure located within the bladder to block the bladder neck to cause urine to collect in the bladder and prevent urine from contacting an anastomosis site.

Support for claim 30 can be found, e.g., at original claim 3.

Support for claim 31 can be found, e.g., at original claim 8.

Cited Prior Art and the Pending Claims

Prior rejections of the pending claims have been based on 35 USC section 103(a) as being unpatentable over Bander (U.S. Patent No. 6,299,598), of Seiba (U.S. Publ. No. 20030229364), and Biggs et al. (U.S. Patent No. 6,599,311).

The claims, as pending with this Submission, are believed to be novel and non-obvious over the cited references.

Claim 1 recites an anastomosis device that includes a hollow, elongate, flexible catheter body having a proximal end and a distal end. The distal end includes an inflatable balloon and a drainage aperture. According to the claim, the inflatable balloon is on a proximal side of the drainage aperture. Further according to the claim, a tissue approximating structure is on a proximal side of the balloon. Thus, claim 1 requires structural features of a tissue approximating structure at a distal end of a catheter body, a balloon that is distal to the tissue approximating structure, and a drainage aperture that is distal to the balloon.

The references of record do not suggest this structure.

The Bander reference requires a different configuration, and modification of the Bander device to meet the features of claim 1 would serve no purpose; thus, there would have been no motivation to modify Bander to meet the features of claim 1. Also, none of the other cited references overcome this shortcoming of the Bander reference, and claim 1 would not have been obvious over the references of record.

In specific, the Bander (which has been the primary reference of record) describes a device that shown for percutaneous insertion into the bladder. Two balloons are located at the distal end. The device is inserted into the bladder through a percutaneous incision at the abdomen. The device within the bladder also places a tip into the urethra. One balloon seals the urethra by being placed and inflated at the bladder neck. The second balloon contacts the opposite side of the bladder at the entry point of the device into the bladder. Because the bladder is sealed (by the balloon), urine can accumulate in the bladder. Apertures located along the body between the two balloons can drain the urine from the bladder.

To function based on the recited method, the balloons of the Bander device must surround the apertures for draining the bladder. There is no purpose to configuring the balloons and apertures at different locations, such as by placing two balloon on a proximal side of an aperture. Without any purpose for that modification there is no motivation for the modification and the modification would not have been obvious to a skilled artisan.

Claim 9, also reciting a configuration as in claim 1, is believed to be patentable over the reference of record for similar reasons.

New claim 26 recites an anastomosis device that includes a body, a drainage aperture, and first and second tissue approximating structure (one of which may optionally be a balloon).

The first and second tissue approximating structure are both located on the proximal side of the drainage aperture. The references of record are not believed to suggest this configuration.

For further consideration is an excerpt found in from the August 2006 issue of the Journal of Endourology (Attachment A). Page A69 discusses a "Virtual Poster Session" VP12-02, that includes a comparison of a "Novel Tissue Apposing Device," to a standard technique. The Novel Tissue Apposing Device is an embodiment of to the inventive devices of the present patent application, which is inserted through the meatus and includes a balloon and tissue approximating structure. During use, the balloon becomes located in the patient's bladder and the tissue approximating structure is located at tissue of the urethra, for anastomotizing the tissue. The description indicates that the novel device requires less time compared to a "standard sutured anastomosis," and that "histopathology revealed that the novel device was superior regarding fibrotic reaction. Advantages of the use of exemplary devices of the invention are also discussed in the original specification, such as at page 3, lines 4 through 28; and at page 20, line 30 through page 21, line 8.

In view of the present amendments and remarks, consideration of the claims as amended, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

Dated: May 17, 2007

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ATTACHMENT A

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VP11-25

ESWL INDUCED RESISTIVE INDEX (RI) CHANGES IN KIDNEY-A MARKER OF ISCHEMIC INJURY: A PROSPECTIVE STUDY

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Introduction: ESWL is considered a relatively safe modality of treatment of selected renal stones. However, it is acutely associated with renal tubular damage and vascular spasms, hematuria & in the long term – hypertension. Ischemia can be assessed satisfactorily by a non invasive method viz. resistive index (RI) using doppler ultrasound. We have carried out this study to assess RI changes due to ESWL.
Method: All patients subjected to ESWL were assessed by doppler study. Baseline & follow up parameters included RI, hematuria (urine Hb), serum creatinine, urinary output & number of shock waves with energy levels. Patients were matched for age, sex, stone burden, characteristics & health status.
Result: From Feb 2005 to Oct 2005 we studied 40 patients with an average age of 40 yrs. (30-54).Average stone bulk was 150mm sq.(70-270).Average number of shocks – 960 (max. energy level of 3).Males – 27 & females – 13.Av. serum creatinine was 1.1. There was significant rise in RI both the side.($p = 0.05$ Change in RI was seen as follows:

For stone bearing side (average)	Preop RI (average)	Postop RI (average)	Change in RI (average)	p
	0.63 (0.59-0.66)	0.78 (0.73-0.86)	0.15 (0.9-0.21)	<0.05
Contralateral side	0.58 (0.52-0.65)	0.62 (0.53-0.68)	0.04 (0.01-0.06)	> 0.05

Conclusion: SWL was seen to induce ischemia in stone bearing renal unit. To begin with, these kidneys had slightly higher RI. Global effect of SWL induced ischemia could not be appreciated on the opposite kidney, although RI did increase post procedure.

VP12-01

COMPARISON OF BIOGLUE REINFORCED AND STANDARD SUTURED VESICOURETHRAL ANASTOMOSES

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Introduction: We compared a BioGlue reinforced laparoscopically sutured vesicourethral anastomosis (VUA) to a standard laparoscopically sutured VUA.
Method: Twelve animals were divided into two groups. In Group 1 ($n = 6$), a standard laparoscopically sutured VUA was performed. In group 2 ($n = 6$), a standard laparoscopic sutured VUA was performed, and the anastomosis was reinforced with BioGlue. Animals in both groups were sacrificed at the 1 week time point. In all cases, a cystogram was performed immediately after completion of the anastomosis, and at the time of sacrifice. At necropsy, gross findings of the vesicourethral anastomosis were documented, and each anastomosis was excised en bloc for an extensive histopathologic evaluation of healing parameters including inflammation and fibrosis at each tissue level, foreign body reaction, and necrosis.
Result: Eleven of the 12 VUA were successfully performed laparoscopically. The median operative time for group 1 and 2 was 70 and 100 minutes, respectively ($p = 0.03$). The median anastomotic time for group 1 and 2 was 30 and 50 minutes, respectively ($p = 0.02$). There was no difference in urinary extravasation on cystogram evaluation in the post-operative or 1-week evaluations. At necropsy, gross complete circumferential histologic tissue approximation was noted in 1/5 (20%) in group 1 and 2/6 (33%) in group 2, ($p = 0.66$). No urinomas were noted in either group. Histopathology revealed no significant difference between groups 1 and 2 regarding inflammation, fibrosis, foreign body reaction and necrosis.
Conclusion: The application of BioGlue to the anastomotic line extended procedure time and did not improve the quality of the VUA.

VP12-02

COMPARISON OF A NOVEL TISSUE APPOSING DEVICE AND STANDARD ANASTOMOTIC TECHNIQUE FOR VESICOURETHRAL ANASTOMOSES

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Introduction: We evaluated a novel sutureless tissue apposing vesicourethral anastomosis (VUA) device in a porcine model and compared it to a standard laparoscopically sutured VUA.
Method: Thirty domestic pigs were divided into six groups. In groups 1, 2, and 3, a standard laparoscopic sutured running VUA was performed. In groups 4, 5, and 6, a novel device VUA was performed. In all cases, a cystogram was completed immediately after completion of the anastomosis and just prior to sacrifice. At necropsy, gross findings of the VUA were documented, and each anastomosis was excised en bloc for histopathologic evaluation of healing parameters.
Result: Twenty nine of thirty (97%) device and sutured VUA were successfully performed laparoscopically. Mean operative time for the standard groups, and device groups was 87 and 68 minutes respectively ($p = 0.04$). The anastomotic time for the standard groups and device groups was 41 and 12 minutes respectively ($p < 0.01$). Histopathological evaluation at one week follow-up revealed significantly lower fibrosis scores for the novel anastomosis device VUA compared to standard sutured VUA (median scores of 1 and 3, respectively ($p = 0.04$)). Evaluation of groups 2 and 5 (3 week survival), and groups 3 and 6 (7 week survival) revealed no significant differences in any of the histopathologic parameters evaluated.
Conclusion: Deployment of the novel device requires little technical skill to deploy and is expeditious requiring less time than a standard sutured anastomosis. At the one week time point, histopathology revealed that the novel device was superior regarding fibrotic reaction.

VP12-03

PNEUMOPERITONEUM WITH CO2 INHIBITS MACROPHAGE TNF-A SECRETION: AN ETIOLOGY FOR TCC PORT SITE METASTASIS AND PROPHYLACTIC IRRIGATION STRATEGIES TO DECREASE ONCOLOGICAL RISK

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Introduction: We hypothesized that attenuated TNF-α secretion from CO2 pneumoperitoneum may alter local immune surveillance and contribute to the development of incisional metastasis. We further sought to determine how port site metastasis could be prevented.
Method: Experiment#1:C57BL/6 Mice were subjected to either CO2 pneumoperitoneum($n = 10$) or a 3 cm incision($n = 10$). Peritoneal macrophages(1×10^6/animal)were collected and TNF-α levels were quantified by immunoassay. Experiment#2:Peritoneal and port site metastasis were evaluated 1 week after 1×10^6 MBT-2 tumor cells/animal were spilled in an open group($n = 5$) and pneumoperitoneal group($n = 5$). Experiment#3:1×10^6 MBT-2 cells/animal were spilled intraperitoneally through trocars of four groups($n = 20$). Port sites in each group were then irrigated with either sterile water, mitomycin(1.0 mg/ml), Betadine(10%), or heparin(1,000 U/ml). At 1 week, incisional sites were evaluated for gross and microscopic metastasis.
Result: Peritoneal macrophage TNF-α secretion was significantly inhibited in mice subjected to CO2 pneumoperitoneum vs. control at 10 minutes($p = 0.015$) and 20 minutes($p = 0.001$). Animals subjected to pneumoperitoneum developed a significantly higher average tumor burden than controls(9.2gm vs. 3.8gm, $p = 0.002$). All irrigants prevented the development of port site metastasis; sterile water did so without toxic effect.
Conclusion: CO2 pneumoperitoneum inhibits peritoneal macrophage TNF-α secretion. Mice subjected to pneumoperitoneum and a tumor challenge develop heavier intraperitoneal and incisional metastasis than open controls. Inhibition of peritoneal macrophage TNF-α may be an adverse event contributing to TCC port site metastasis, especially if surgical oncological principles are violated. Irrigating trocar sites with sterile water at the conclusion of laparoscopic nephroureterectomy and cystectomy offers a safe prophylactic strategy to help prevent this unfavorable event.